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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/257,739 | 02/25/1999 | SHALOM Z. HIRSCHMAN | 4493-36 | 2898 |

7590

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EXAMINER

LE, EMILY M

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/257,739

Applicant(s)

HIRSCHMAN ET AL.

Examiner

Emily Le

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 07, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-9 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Emily Le, Art Unit 1648. The examiner acknowledges Applicant's amendment, Paper No. 20, filed October 07, 2002. In view of Applicant's amendment, the status of the claims is as follows: Claims 5-6 have been canceled; Claims 1-4 and 7-9 are currently pending before the examiner.

The rejection of Claims 1-4 and 7-9 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, with regards to delimiter and comparison of RT-PCR amounts, have been withdrawn in light of Applicant's amendment. Further, The enablement rejection of Claims 1-4 and 7-9 under 35 U.S.C § 112, first paragraph have been withdrawn in light of Applicant's amendment. Applicant has amended "predetermine amount" to "predetermined progressively increasing amount" to obviate the rejection. However, such changes has raised the issue of new matter, see below.

Claim Objections

Claim 1 is objected to because of the following informalities: claim 1 recites two "a" steps. For the purpose of examination, the second "a" will be considered to be "a". In addition, "weigh" should be "weight" in the second "a". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection. Applicant introduced new matter in applicant's amendment, filed October 07, 2002, of claims 1 and 7. The examiner cannot find support within the original specification for the insertion of "concentrations between 0 to 100% by volume" of product R as claimed in step C of claim 1 and step B of claim 7. Secondly, the new matter rejection also applies to "parts by weight" as recited in step "a" of claims 1 and 7. Support for the insertion of "parts by weight" within the specification was not found. However, it is noted that the specification does provide support for "grams" (page 9, line 6) **NOT** "parts by weight". Lastly, support cannot be found in the original specification for the insertion of "a smaller amount of said RT-PCR product correlates a lower level of said gene expression".

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

Claims 1-4 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for adjustment of the pH of product R to 7.3-7.6 range, does not reasonably provide enablement for "physiologically acceptable pH range" as recited in step f) of claims 1 and 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant is enabled for the pH range of only 7.3 to 7.6 as taught on page 9, line 20, of specification. Further, the recitation of "between 0 to 100% by volume" is not enabled by the specification. However, the specification is enabled for 0%, 25%, 50%, 75% and 100%.

Claims 1-4 and 7-9 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The recitation of "predetermine progressively increasing amounts" of Product R into a plurality of cultures in claims 1-4 and 7-9 does not enable one skilled in the art to make or use the invention. The specification does not provide any guidance concerning "predetermine progressively increasing amounts" such as the frequency and rate of addition of Product R into the cell cultures and concentration of Product R to be added to each cell cultures. Applicant has not provided sufficient guidance to allow one skilled in the art to practice the claimed invention without undue experimentation. In the absence of such guidance, the specification fails to provide an enabling disclosure.

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The claims are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Step c' recites "cooling of product" without disclosure of the rate and period of cooling in the specification. It appears, from the specification, that the rate and period of cooling of Product R is critical to the invention. The disclosure of "cool for at least six hours at about 3-8 degrees Celsius" is vague, thus, not enabling the claimed invention. The specification fails to enable the claimed invention.

Further, the specification has also failed to enable the claimed invention with the recitation of "adding water" in step e'. The disclosure of "a calculation is then performed to determine the quantity of cooled water for injection to be added" in the specification is not enabling for the claimed invention. The disclosure lacks specific guidance as to the formula or type of calculation made to make such assessment.

In view of the above reasons, one skilled in the art would not be able to make and use the claimed invention with a reasonable expectation of success and without undue experimentation. Therefore, the specification fails to provide enabling disclosure for the claimed invention.

Conclusion

No claim is allowed. The claimed invention appears free of the art for the reasons set forth in the previous Office Action.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

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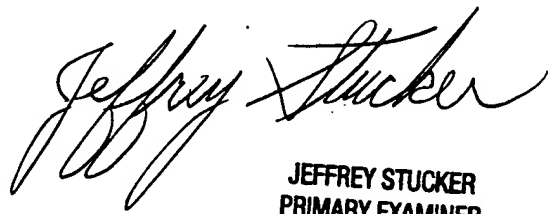
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (703) 305-4452.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0169.

emle
August 25, 2003



JEFFREY STUCKER
PRIMARY EXAMINER